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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,234	11/13/2003	Lawrence M. Kauvar	388512010410	1178

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,234

Applicant(s)

KAUVAR, LAWRENCE M.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19 and 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 14-17, 19, 21-31 are currently pending.
2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Objections

3. Claim 14 objected to because of the following informalities: instead of utilizing parentheses to describe toxic conditions and normal conditions, it would be greatly appreciated if applicant could use commas instead or otherwise clarify in the claims that “in the presence of toxic compound” defines toxic conditions and “in the absence of toxic compound” defines normal conditions, and are not just examples of the respective conditions.
4. In line 12 of claim 14, “a antidote compound” should be an antidote compound.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 14-17, 19, 21-22, 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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7. In claim 14, applicant has recited “an antidote” in the preamble, as well as “a candidate antidote” and “a antidote compound”. It is unclear whether these antidotes all refer to the same antidote, or to different antidotes. Clarification would be greatly appreciated.

8. Claims 14, 17 recite the limitation "the intracellular localization pattern" in the third line of claim 14 and in the fifth line of claim 17. There is insufficient antecedent basis for this limitation in the claim. It should also be noted that applicant uses “the localization pattern” and “said pattern” throughout the claims and also in claim 19. While it is believed that both these patterns refer to the intracellular localization pattern, further confirmation would be greatly appreciated.

9. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 14-17, 19, 21-22, 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Carayon et al [Carayon et al, Involvement of peripheral benzodiazepine receptors in the protection of hematopoietic cells against oxygen radical damage, 1996, Blood, Vol. 87 (7), 3170-3178].

With respect to claims 14-16, Carayon et al teach observing localization of Bcl-2 and PBR in mitochondrial outer membrane in cells (p.3174, col.1). In particular, Carayon et al teach

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observation of Bcl-2 and PBR in cells that are resistant to ROS damage (normal conditions, where the concentration of H_2O_2 can be resisted, and would not be toxic to the cells) and in JURKAT cells, which are not resistant to ROS damage (toxic conditions, where the concentration of H_2O_2 cannot be resisted and would be toxic to the cells). Carayon et al further teach transfection of an expression vector containing the human PBR cDNA (antidote), and the PBR and Bcl-2 expression when the effect of H_2O_2 on the cells (antidote in toxic conditions) is studied (p.3174, col.2). The distribution of PBR is studied using a laser scanning confocal microscope (p.3171, col. 2, pg. 3), and where the cells were fixed (p.3171, col.2, pg.5).

12. With respect to claims 17, 19, 21-22, Carayon et al teach observing localization of Bcl-2 and PBR in mitochondrial outer membrane in cells (p.3174, col.1). In particular, Carayon et al teach observation of Bcl-2 and PBR in normal cells and in JURKAT cells, which do not express endogenous PBRs (p.3176, col.1, pg.2). Carayon et al further teach expression of JURKAT cells when transfected with an expression vector containing the gene for the human PBR (p.3176, col.1, pg.2). Carayon et al notes that tumor necrosis factor cytotoxicity is mediated by early damage of mitochondrial function induced by ROS, and suggests that overexpression of PBRs may protect cells from death (p.3176, col.2, pg.3). Carayon et al further teach transfection of an expression vector containing the human PBR cDNA (antidote), and the PBR and Bcl-2 expression when the effect of H_2O_2 on the cells (antidote in toxic conditions) is studied (p.3174, col.2). The distribution of PBR is studied using a laser scanning confocal microscope (p.3171, col. 2, pg. 3), and where the cells were fixed (p.3171, col.2, pg.5).

13. With respect to claims 26-28, the distribution of PBR is studied using a laser scanning confocal microscope (p.3171, col. 2, pg. 3).

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14. With respect to claims 29-31, the cells were fixed (p.3171, col.2, pg.5).

Response to Arguments

15. Applicant's arguments, see p. 2-5, filed January 24, 2005, with respect to the rejection of claims 14-17, 19, 21-31 under 35 U.S.C. 102(a) as being anticipated by Gasman et al [Gasman et al, Identification of a potential effector pathway for the trimeric G_o protein associated with secretory granules, 1998, J Bio Chem, 273(27), p.16913-16920] have been fully considered and are persuasive. The rejection of claims 14-17, 19, 21-31 under 35 U.S.C. 102(a) as being anticipated by Gasman et al has been withdrawn.

Allowable Subject Matter

16. Claims 23-25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

17. No claims are allowed.

18. The following references are also cited as art of interest: Kroemer et al [Kroemer et al, The mitochondrial death/life regulator in apoptosis and necrosis, 1998, Annu Rev Physio, 60:619-42] discusses apoptosis and necrosis in cells and factors involved in cell death and the cell death pathway.


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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE
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09/07/05